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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0678; FRL-9927-19]

Alkyl (C₈₋₂₀) Polyglucoside Esters; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of D-glucopyranose, oligomeric, 6-(dihydrogen citrates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts; D-glucopyranose, oligomeric, 6-(hydrogen sulfosuccinates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts; and D-glucopyranose, oligomeric, lactates, C₈₋₂₀ branched and linear alkyl glycosides when used as an inert ingredients (surfactants) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. Lamberti USA, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of D-glucopyranose, oligomeric, 6-(dihydrogen citrates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts: D-glucopyranose, oligomeric, 6-(hydrogen sulfosuccinates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts; and D-glucopyranose, oligomeric, lactates, C₈₋₂₀ branched and linear alkyl glycosides.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after*

date of publication in the Federal Register], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0678, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDfrNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0678 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the

non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0678, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Petition for Exemption

In the **Federal Register** of October 15, 2014 (79 FR 61844) (FRL-9917-24), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10675) by Lamberti USA, Inc., 161 Washington St., Conshohocken, PA 19428. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of D-glucopyranose, oligomeric, 6-(dihydrogen citrates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts (CAS Reg. No. 1079993-97-7); D-glucopyranose, oligomeric, 6-(hydrogen sulfosuccinates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts (CAS Reg. No. 1079993-92-2); and D-glucopyranose, oligomeric, lactates, C₈₋₂₀ branched and linear alkyl glycosides (CAS Reg. No. 1079993-94-4) (hereafter referred to in this document as alkyl polyglucoside (C₈₋₂₀) esters or AGEs) when used as inert ingredients (surfactants) in pesticide formulations applied to growing crops and raw agricultural commodities. That document referenced a summary of the petition prepared by Lamberti USA

Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit V.C.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is

a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for alkyl polyglucoside (C₈₋₂₀) esters including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with alkyl polyglucoside (C₈₋₂₀) esters follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by alkyl

polyglucoside (C₈₋₂₀) esters as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit. Limited toxicity data are available on D-glucopyranose, oligomeric, 6-(dihydrogen citrates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts; D-glucopyranose, oligomeric, 6-(hydrogen sulfosuccinates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts; and D-glucopyranose, oligomeric, lactates, C₈₋₂₀ branched and linear alkyl glycosides. The alkylpolyglucoside (C₈-C₂₀) esters are reaction products of glucose and fatty acids in which the alcohol moiety is attached to the polyglucoside by a β -glucosides linkage. The toxicity profile of these substances is based upon data from other, related alkyl polyglucoside esters sharing similar physical and chemical characteristics as well as expected toxicity as well as AGE metabolites lactic acid, citric acid and disodium sulfosuccinate.

AGEs have low acute toxicity via the oral route (oral LD₅₀ > 5,000 milligram/kilogram (mg/kg)). There is no available data regarding acute exposure via the dermal, eye or inhalation routes.

In a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats (OCSPP Guideline 870.3650 study), there were no observed adverse effects for parental systemic or reproductive/developmental toxicity at 1,000 mg/kg/day.

A 2-year chronic oral study in rats treated with citric acid was available for review. Rats were administered 5 percent or 3 percent citric acid (approx. 2,000 or 1,200 mg/kg/day) in the diet. There were no adverse effects observed at 2,000 mg/kg/day. Chronic studies were also available for the rabbit and dog. There were no adverse effects observed in either study at doses up to 1,500 and 1,400 mg/kg/day, respectively.

Neurotoxicity studies with AGEs were not available for review. However, neurotoxicity was not observed in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test at concentrations as high as 1,000 mg/kg/day (limit dose).

Mutagenicity studies on several surrogate chemicals did not indicate positive response for mutagenic effects. The Agency further evaluated the carcinogenic potential of alkyl polyglucoside (C₈₋₂₀) esters by conducting a knowledge base qualitative structure activity relationship (SAR) database search, DEREK Nexus Version 2.0, to determine if there were structural alerts. No structural alerts were identified including carcinogenicity.

Alkylpolyglycosides are rapidly hydrolyzed in intestine and liver. The cleavage products, sugars and long-chain alcohols, enter the pathways of lipid and carbohydrate metabolism.

Specific information on the studies received and the nature of the adverse effects caused by, can be found at <http://www.regulations.gov> in the document “PC Codes 911028, 911029, 911030: Alkyl (C₈₋₂₀) polyglucoside Esters (AGEs); Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations.” at (6) in docket ID number EPA-HQ-OPP-2014-0678.

B. Toxicological Points of Departure/Levels of Concern

Alkylglycosides are rapidly hydrolyzed in intestine and liver. The cleavage products, sugars, and long-chain alcohols enter the pathways of lipid and carbohydrate metabolism. Based on the low acute toxicity of AGEs, the body’s ability to rapidly metabolize these substances, the expected metabolites being fatty acids and carbohydrates (which are normal constituents of the body), and the lack of observed adverse effects for repeat dose studies at the limit dose (1,000 mg/kg/day), no endpoint of concern was identified.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to alkyl polyglucoside (C₈₋₂₀) esters, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from alkyl polyglucoside (C₈₋₂₀) esters in food as follows:

Dietary exposure to AGEs can occur from eating food treated with alkyl polyglucoside (C₈₋₂₀) esters. However, a quantitative assessment was not conducted since an endpoint of concern for risk assessment was not identified.

2. *Dietary exposure from drinking water.* Dietary exposure from drinking water to alkyl polyglucoside (C₈₋₂₀) esters can occur by drinking water that has been contaminated by run-off from a pesticide treated area. Since an endpoint for risk assessment was not identified, a quantitative dietary exposure assessment from drinking water for alkyl polyglucoside (C₈₋₂₀) esters was not conducted.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Alkyl polyglucoside (C₈₋₂₀) esters have reported uses in personal care products, such as antiperspirants, shampoos, conditioners, and moisturizers. Residential exposure to alkyl polyglucoside (C₈₋₂₀) esters via the oral, dermal, and inhalation route of exposure is also possible as a result of their use as inert ingredients in registered pesticide products that include residential uses. However, since there is toxicological endpoint identified, it is not necessary to conduct assessments of residential (non-occupational) exposures and risks.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or

revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found Alkyl polyglucoside (C₈₋₂₀) esters to share a common mechanism of toxicity with any other substances, and Alkyl polyglucoside (C₈₋₂₀) esters do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that Alkyl polyglucoside (C₈₋₂₀) esters do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infant and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. The database is considered adequate for FQPA assessment. Fetal susceptibility was not observed in the combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in the rat. There were no toxic effects observed in either study at the highest doses tested, 1,000 mg/kg/day. Signs of neurotoxicity were not observed in any of the submitted studies. No treatment related effects in a functional observational battery - (FOB)

and on motor activity parameters were observed at doses up to 1,000 mg/kg/day; EPA has concluded that a developmental neurotoxicity study is not required. Signs of potential immunotoxicity were not observed in any of the submitted studies. Based on its assessment of available data for AGEs as discussed in Unit IV.A., EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children, and has conducted a qualitative assessment. As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on D-glucopyranose, oligomeric, 6-(dihydrogen citrates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts; D-glucopyranose, oligomeric, 6-(hydrogen sulfosuccinates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts; and D-glucopyranose, oligomeric, lactates, C₈₋₂₀ branched and linear alkyl glycosides, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to D-glucopyranose, oligomeric, 6-(dihydrogen citrated), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts; D-glucopyranose, oligomeric, 6-(hydrogen sulfosuccinates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts; and D-glucopyranose, oligomeric, lactates, C₈₋₂₀ branched and linear alkyl glycosides under reasonable foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 for residues of D-glucopyranose, oligomeric, 6-(dihydrogen citrates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts; D-glucopyranose, oligomeric, 6-(hydrogen sulfosuccinated), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts; and D-glucopyranose, oligomeric, lactates, C₈₋₂₀ branched and linear alkyl glycosides when used as inert ingredients in pesticide formulations

applied to growing crops and raw agricultural commodities after harvest, is safe under FFDCA section 408.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. Response to Comments

One comment was received in response to the notice of filing. The comment received was from a private citizen who opposed any pesticide product that leaves a residue above 0.00. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by FFDCA section 408, EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for D-glucopyranose, oligomeric, 6-(dihydrogen citrates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts (CAS Reg. No. 1079993-97-7); D-glucopyranose, oligomeric, 6-(hydrogen sulfosuccinates), C₈₋₂₀ branched and linear alkyl glycosides, sodium salts (CAS Reg. No. 1079993-92-2); and D-glucopyranose, oligomeric, lactates, C₈₋₂₀ branched and linear alkyl glycosides (CAS Reg. No. 1079993-94-4) esters when used as inert ingredients (surfactants) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus,

the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 18, 2015.

Daniel J. Rosenblatt,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Amend § 180.910 by adding alphabetically the following inert ingredients to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
D-glucopyranose, oligomeric, 6-(dihydrogen citrates), C ₈₋₂₀ branched and linear alkyl glycosides, sodium salts (CAS Reg. No. 1079993-97-7)		Surfactant
D-glucopyranose, oligomeric, 6-(hydrogen sulfosuccinates), C ₈₋₂₀ branched and linear alkyl glycosides, sodium salts (CAS Reg. No. 1079993-92-2)		Surfactant
D-glucopyranose, oligomeric, lactates, C ₈₋₂₀ branched and linear alkyl glycosides (CAS Reg. No. 1079993-94-4)		Surfactant
* * *	* *	* *